

02-33000-23

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Reviewed: 08/24/23

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## Subject: Heart Transplant

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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### DESCRIPTION:

A heart transplant or retransplant consists of replacing a diseased heart with a healthy donor heart. Transplantation is used for individuals with refractory end-stage cardiac disease.

Heart failure is the reduction of cardiac output and is considered severe when systemic circulation cannot meet the body's needs under minimal exertion. Heart transplantation can potentially improve both survival and quality of life in those with end-stage heart failure.

Heart failure may be due to a number of differing etiologies, including ischemic heart disease, cardiomyopathy, or congenital heart defects.

### POSITION STATEMENT:

#### Certificate of Medical Necessity

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

1. Click the link Solid Organ Transplant under Certificates of Medical Necessity in the side navigation of this page to access the form.
2. Complete all fields on the form thoroughly.
3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

Human heart transplantation **meets the definition of medical necessity** for adults and children with end-stage heart failure when selection criteria are met.

### **Adult transplantation**

Accepted indications for cardiac transplantation:

1. Hemodynamic compromise due to heart failure demonstrated by any of the following:
  - Maximal VO<sub>2</sub> (oxygen consumption) <10 mL/kg/min with achievement of anaerobic metabolism
  - Refractory cardiogenic shock
  - Documented dependence on intravenous inotropic support to maintain adequate organ perfusion, **OR**
2. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty, **OR**
3. Recurrent symptomatic ventricular arrhythmias refractory to **ALL** accepted therapeutic modalities

Probable indications for cardiac transplantation:

1. Maximal Vo<sub>2</sub> <14 mL/kg/min and major limitation of activities, **OR**
2. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty, **OR**
3. Instability of fluid balance/renal function not due to noncompliance with regimen of weight monitoring, flexible use of diuretic drugs, and salt restriction

### **Pediatric transplantation**

Accepted indications for cardiac transplantation:

1. Heart failure with persistent symptoms at rest who require one or more of the following:
  - Continuous infusion of intravenous inotropic agents, **OR**
  - Mechanical ventilatory support, **OR**
  - Mechanical circulatory support, **OR**
2. Pediatric heart disease with symptoms of heart failure who do not meet the above criteria but who have:
  - Severe limitation of exercise and activity (if measurable, such candidates would have a maximum VO<sub>2</sub> <50% predicted for age and sex), **OR**
  - Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease, **OR**
  - Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator, **OR**
  - Restrictive cardiomyopathy with reactive pulmonary hypertension, **OR**
  - Reactive pulmonary hypertension and risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future, **OR**
  - Anatomic and physiologic conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle, **OR**

- Anatomic and physiologic conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction

Heart retransplantation after a failed primary cardiac transplant **meets the definition of medical necessity** in individuals who meet criteria for heart transplantation.

Heart transplantation is considered **experimental or investigational** in all other situations, as available clinical evidence does not support safety and effectiveness.

Potential contraindications to cardiac transplantation (subject to the judgment of the transplant center) include:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to heart or lung disease
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy
- Pulmonary hypertension that is fixed as evidenced by pulmonary vascular resistance >5 Wood units, or transpulmonary gradient  $\geq 16$  mm/Hg despite treatment
- Severe pulmonary disease, despite optimal medical therapy, not expected to improve with heart transplantation

## BILLING/CODING INFORMATION:

### CPT Coding:

33940	Donor cardiectomy, including cold preservation.
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation.
33945	Heart transplant, with or without recipient cardiectomy

## REIMBURSEMENT INFORMATION

None applicable.

### PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage:** The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: National Coverage Determination (NCD) for Heart Transplants (260.9), located at [cms.gov](https://www.cms.gov).

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#)

## DEFINITIONS:

No guideline specific definitions apply.

## RELATED GUIDELINES:

[Heart and Lung Transplant, 02-33000-24](#)

[Ventricular Assist Devices and Total Artificial Hearts, 02-33000-25](#)

## OTHER:

**Florida Statute 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited. (excerpt)**

(3)(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

**Florida Statute 627.64197 Coverage for organ transplants.**—A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

**Florida Statute 627.65736 Coverage for organ transplants.**—A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

**Florida Statute 641.31075 Coverage for organ transplants.**—A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance organization to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

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### COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/24/23.

### GUIDELINE UPDATE INFORMATION:

01/01/01	Medical Coverage Guideline developed.
12/15/02	Reviewed and revised; statement was added regarding transplant facilities.
07/01/03	HCPCS coding update.
11/15/04	Scheduled review; added statement regarding organ transplants in HIV-positive recipients.
01/01/05	HCPCS coding update: added 33944, revised 33940 descriptor.

06/15/05	Revision to guideline, consisting of removal of investigational statement regarding HIV-positive recipients.
06/15/06	Scheduled review; no change in coverage statement.
06/15/07	Scheduled review (consensus); no change in coverage; reformatted guideline; updated references.
07/15/08	Scheduled review; no change in position statement. Update references.
07/15/09	Scheduled review; no change in position statement. Update description section with addition of status 7 listing from UNOS. Update reference section.
06/15/14	Scheduled review. Revised description, position statement, CPT coding and program exceptions. Updated references.
12/15/19	Scheduled review. Revised description and contraindications. Updated references.
02/15/20	Revision: Deleted UNOS status criterion.
07/01/20	Revision: added Florida statute language regarding discrimination in access to anatomical gifts and coverage of organ transplants. Updated references.
09/15/21	Scheduled review. Maintained position statement and updated references.
05/23/23	Update to Program Exceptions section.
09/15/23	Scheduled review. Maintained position statement and updated references.